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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/872,127	06/01/2001	Anker Jon Hansen	5776.204-US	1919
7590	10/06/2003			
Reza Green, Esq. Novo Nordisk of North America, Inc. Suite 6400 405 Lexington Avenue New York, NY 10174-6401			EXAMINER COOK, REBECCA	
			ART UNIT 1614	PAPER NUMBER
			DATE MAILED: 10/06/2003 12	

Please find below and/or attached an Office communication concerning this application or proceeding.

**Office Action Summary**

Application No.

09/872,127

Applicant(s)

HANSEN ET AL.

Examiner

Jerome D Goldberg

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☒ Responsive to communication(s) filed on 09 July 2003.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 1-34 is/are pending in the application.
- 4a) Of the above claim(s) 6-33 is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1,2,4,5 and 34 is/are rejected.
- 7) ☒ Claim(s) 3 is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on \_\_\_\_\_ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

**Priority under 35 U.S.C. §§ 119 and 120**

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \* See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

**Attachment(s)**

- 1) ☒ Notice of References Cited (PTO-892) 4) ☐ Interview Summary (PTO-413) Paper No(s). \_\_\_\_\_
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948) 5) ☐ Notice of Informal Patent Application (PTO-152)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) \_\_\_\_\_ 6) ☐ Other: \_\_\_\_\_

This application contains claims 6-33 drawn to an invention nonelected with traverse in Paper No. 8. A complete reply to the final rejection must include cancellation of nonelected claims or other appropriate action (37 CFR 1.144) See MPEP § 821.01.

Cancellation of claims 6-33 is now required.

The instant claims 1-5 and 34 are still being examined as they read as the compounds wherein  $Y \Rightarrow N-CH_2$ , p and q= O and 1,  $X = CH-CH_2$  or  $CH_2-CH_2-CH_2$  and Z= piperidinecarboxylic acid.

Claims 1-2, 4, 5 and 34 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for the specific cancer disclosed, does not reasonably provide enablement for the term "a condition related to angiogenesis" or "cancer". The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to use the invention commensurate in scope with these claims. The terms a condition related to angiogenesis in claim 1, 4, 5 and 34 and "cancer" in claim 2 lacks clear exemplary support in the specification as filed.

Applicants' remarks are noted but the claims are directed to treating "cancer" per se (see claim 2), <sup>40</sup>Moreover, enablement is considered in view of the Wands factors (MPEP 2164.01 (a)). These include: nature of the invention, breadth of the claims, guidance of the specification, the existence of working examples, predictability of the prior art, state of the prior art the amount of experimentation necessary all of the wands factors have been considered with regard to the instant claims, with the most relevant factors discussed below.

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Nature of the invention: claims 1, 2, 4, 5 and 34 are drawn to treating cancer broadly in human patients.

Breadth of the claims: the complex nature of the claim greatly exacerbated by breadth of the claims. The claims encompass treating cancer broadly in human patients.

Guidance of the specification:

The guidance given by the specification as to how one would administer the claimed compounds to a subject in order to treating cancer broadly. The guidance provided by the specification is directed to specific cancer in a specific concentration of the claimed compounds.

Working examples: all the working examples provided by the specification are directed to specific cancers.

State of the art: while the state of the art is relatively high with regard to treatment of specific cancers, the state of the art with regard to single agent for treating cancer broadly is underdeveloped. In particular, there is no known anticancer agent which is effective against all cancers. The Carter et al reference clearly teaches that for the forty known anticancer agents, none are effective against all cancers. (See pages 362-365 of Carter et al reference).

Predictability of the art: the lack of significant guidance from the specification or prior art with regard to the actual treatment of all cancers in human patients with the claimed compounds makes practicing the claimed invention unpredictable.

The quantity of experimentation necessary:

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Applicants fail to provide guidance and information to allow the skilled artisan to ascertain which particular type of cancer the claimed anticancer agent is effective against without undue experimentation. The limited disclosure of several cancer is noted but will not support all cancers being claimed. The Carter et al reference shows data on twenty-three types of cancer. Applicants should at least test these types of cancer with the claimed anticancer agent.

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Claims 1, 2, 4, 5 and 34 are rejected under 35 U.S.C. 103(a) as being unpatentable over the Jargensen et al. WO 96/31497 publication of record for the reasons fully set forth in paper no.9, pages 3 and 4.

Applicants' remarks are noted but the claims are directed to treating a "condition..." and claim 2 states that the condition is "cancer".

The prior art teaches a position isomer for treating cancer, i.e. cancer pain. Clearly this reads on the instant claims of "treating" cancer not inhibiting cancer.

Claim 3 is objected to as depend on a rejected claim 1.

**THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Examiner J. D. Goldberg whose telephone number is (703) 308-4606. The examiner can normally be reached on Monday-Thursday 9:00 A.M - 3:00 P.M.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Marianne Seidel can be reached on (703) 308-4725. The fax phone

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number for the organization where this application or proceeding is assigned is (703) 872-9306.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-1235.

Goldberg/tgd  
October 2, 2003

A handwritten signature in black ink, appearing to read 'Jerome D. Goldberg', written in a cursive style.

**JEROME D. GOLDBERG  
PRIMARY EXAMINER**